## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: BUXTON1 Conf. No.: In re Application of: Francis Paul BUXTON et al. IA No: PCT/EP2003/014089 Art Unit: IA Filed: December 11, 2003 Examiner: Washington, D.C. Appln. No.: Not yet assigned June 10, 2005 For: METHODS FOR DISGNOSING AND)

TREATING SCHIZOPHRENIA

## INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents U.S. Patent and Trademark Office Customer Service Window Randolph Building, Mail Stop Amendment 401 Dulany Street Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the aboveidentified application, and any other application relying on the filing date of the above-identified application or crossreferencing it as a related application.

- [X] 1. This IDS should be considered, in accordance with 37 CFR \$1.97, as it is filed:
- [X] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- [ ] B. before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR \$1.114; or

- [ ] C. after (A) and (B) above, but before final rejection or allowance, and Applicant has made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below):
  - [ ] i. Counsel certifies that, upon information and belief, each item of information listed herein either was
    - [ ] (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
    - [ ] (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR \$1.56(c) more than three months prior to the filing of this IDS.
  - [] ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR \$1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.
- [X] 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:
- [ ] A. Document(s) \_\_\_\_\_ is/are deemed substantially cumulative to document(s) , and,

in accordance with 37 CFR \$1.98(c), a copy of each of the former document(s) is not enclosed.

[ ] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications)

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449, PTO/SB/08a and/or PTO/SB/08b (or their BN form equivalents) from the files of the prior application(s) or a fresh BN/SB/08A and/or BN/SB/08B listing these documents, and request that they be considered and made of record in accordance with 37 CFR \$1.98(d). Per 37 CFR

application.

[ ] 3. Document(s) \_\_\_\_ is/are not in the English language. In accordance with 37 CFR \$1.98(a)(3), Applicant states:

\$1.98(d), copies of these documents need not be filed in this

- [ ] An English translation of each document \_\_\_\_ (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.
- [ ] For documents \_\_\_\_\_\_, a corresponding English-language patent or published application is included on the accompanying Form BN/SB/08A, with a line drawn in the margin connecting the non-English-language document with its corresponding English-language document.
- [ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is found in the attached \_\_\_\_\_ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [ ] A concise explanation of the relevance of document(s) \_\_\_\_\_ is set forth as follows:

In re Appln. of BUXTON1

10/538339 JC20 Rec'd PCT/PTO 10 JUN 2005

| L   | A concise explanation | of the relevance of     |
|-----|-----------------------|-------------------------|
|     | document(s)           | can be found on page(s) |
|     | of the speci:         | fication.               |
| [ ] | A concise explanation | of the relevance of     |
|     | document(s)           | can be found on the     |
|     | attached sheet.       |                         |

- [X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [X] 5. Other information being provided for the examiner's consideration follows:

International Search Report

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK
Attorneys for Applicant(s)

By:

<del>Allen C.</del> Yun

Registration No. 37,971

ACY: 1mh

624 Ninth Street, N.W., Suite 300

Washington, D.C. 20001-5303

Telephone: (202)628-5197 Facsimile: (202)737-3528

G:\BN\U\UMB\Buxton1\pto\ids.fee.doc

| Substitute fo                                 | Substitute for form 1449A/PTO |      |           | Complete if Knewn 770  |                       |  |
|---|-------------------------------|------|-----------|------------------------|-----------------------|--|
|   |                               |      |           | Application Number     | Not/yeldssigned 7 7 7 |  |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT |                               |      |           | Filing Date            | Even date herewith    |  |
|   |                               |      |           | First Named Inventor   | Francis Paul BUXTON   |  |
|   |                               |      |           | Group Art Unit         |                       |  |
|   | (use as many sheets           | as n | ecessary) | Examiner Name          |                       |  |
| Sheet   | 1                             | of   | 2         | Attorney Docket Number | BUXTON1               |  |

|                   |              |  | U.S. PATE                      | NT DOCUMENTS                                       |   |
|-------------------|--------------|--|--------------------------------|--|---|
| Examiner nitials* | Cite<br>No.1 | Document Number Number-Kind Code <sup>2 (ff</sup> known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                   |              | US-  |                                |  |   |
|                   |              | US-  |                                |  |   |
|                   |              | US-  |                                |  |   |
|                   |              | US-  |                                |  | -   |
|                   |              | US-  |                                |  |   |

|           | FOREIGN PATENT DOCUMENTS |  |                             |   |   |                |  |  |  |
|-----------|--------------------------|--|-----------------------------|---|---|----------------|--|--|--|
| Examiner  |                          | Foreign Patent Number Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |  |  |  |
| Initials* | No.1                     | known)   |                             |   | of Relevant Figures Appear  | L <u>'</u>     |  |  |  |
|           | AA                       | WO 02/079218 A1  | 10-10-2002                  | Wyeth   |   |                |  |  |  |
|           | AB                       | WO 03/078658 A2  | 09-25-2003                  | Novartis AG                                     |   |                |  |  |  |
|           |                          |  |                             |   |   |                |  |  |  |
|           |                          |  |                             |   |   |                |  |  |  |
|           |                          |  |                             |   |   |                |  |  |  |
|           |                          |  |                             |   |   |                |  |  |  |
|           |                          |  |                             |   | , ,   |                |  |  |  |
|           |                          |  |                             |   |   |                |  |  |  |
|           |                          |  |                             |   |   |                |  |  |  |
|           |                          |  |                             |   |   | İ              |  |  |  |
|           |                          | -  |                             |   |   |                |  |  |  |
|           |                          |  |                             |   |   |                |  |  |  |

|           | <br>       |  |
|-----------|------------|--|
| Examiner  | Date       |  |
| Signature | Considered |  |

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols sindicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

## JC20 Rec'd PCT/PTO 1 0 JUN 2005.

| Substitute for form 1449A/PTO |                    |        |           | one of the state |                     |  |
|-------------------------------|--------------------|--------|-----------|--|---------------------|--|
|                               |                    |        |           | Application Number   | Not yet assigned    |  |
| INFORMATION DISCLOSURE        |                    |        |           | Filing Date  | Even date herewith  |  |
| STATEMENT BY APPLICANT        |                    |        | PLICANT   | First Named Inventor   | Francis Paul BUXTON |  |
| •                             |                    |        | ,         | Group Art Unit   |                     |  |
|                               | (use as many sheet | s as n | ecessary) | Examiner Name  |                     |  |
| Sheet                         | 2                  | of     | 2         | Attorney Docket Number   | BUXTON1             |  |

|                       |              | OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS  |    |
|-----------------------|--------------|--|----|
| Examiner<br>Initials* | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published                                       | T² |
|                       | AC           | Benes, F.M. et al., "Increased GABA <sub>A</sub> receptor binding in superficial layers of cingulate cortex on schizophrenics", The Journal of Neuroscience, (March 1992), Vol. 12, No. 3, pp. 924-929.  |    |
|                       | AD           | Dolan, R.J. et al., "Dopaminergic modulation of impaired cognitive activation in the anterior cingulate cortex in schizophrenia", Nature, (Nov. 9, 1995), Vol. 378, No. 6553, pp. 180-182.   |    |
|                       | AE           | Evans, S.J. et al., "DNA microarray analysis of functionally discrete human brain regions reveals divergent transcriptional profiles", Neurobiology of Disease, (Nov. 2, 2003), Vol. 14, No. 2, pp. 240-250.   |    |
|                       | AF           | Hakak, Y. et al., "Genome-wide expression analysis reveals dysregulation of myelination-related genes in chronic schizophrenia", PNAS, (April 10, 2001), Vol. 98, No. 8, pp-4746-4751.   |    |
| . ,                   | AG           | Harrison, P.J., "The neuropathology of schizophrenia. A critical review of the data and their interpretation", Brain, (1999), Vol. 122, pp. 593-624.   |    |
|                       | AH           | Mirnics, K. et al., "Analysis of complex brain disorders with gene expression microarrays: schizophrenia as a disease of the synapse", Trends in Neuroscience, (August 1, 2001), Vol. 24, No. 8, pp. 479-486.  |    |
|                       | AI           | Tamminga, C.A. et al., "The limbic cortex in schizophrenia: focus on the anterior cingulate", Brain Research Reviews, (2000), Vol. 31, pp. 364-370.  |    |
|                       | AJ           | Mundo, E. et al., "Monocyte chemoattractant protein-1 gene and schizophrenia", American Journal of Medical Genetics, (Oct. 8, 2002), Vol. 114, No. 7, pg. 863.   |    |
|                       | AK           | Schwarz, M.J. et al., "T-helper-1 and T-helper-2 Responses in Psychiatric Disorders", Brain, Behavior, and Immunity, (Dec. 2001), Vol. 15, No. 4, pp. 340-370.   |    |
|                       | AL           | Teuscher, C. et al., "Sequence Polymorphisms in the Chemokines Sca1 (TCA-3), Scya2 (Monocyte Chemoattractant Protein (MCP)-1), and Scya12 (MCP-5) Are Candidates for eae7, a Locus Controlling Experimental Allergic Encephalomyelitis", Journal of Immunology, (1999), Vol. 163, pp. 2262-2266. |    |
|                       | AM           | Vawter, M.P. et al., "Application of cDNA microarrays to examine gene expression differences in schizophrenia", Brain Research Bulletin, (July 2001), Vol. 55, No. 5, pp. 641-650.   |    |
|                       |              |  |    |
|                       |              |  |    |

| Examiner  | Date       |  |
|-----------|------------|--|
| Signature | Considered |  |

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.